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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,627	09/26/2002	Mark Anthony Fernance Kendall	KEMP002	8277

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EXAMINER

HUH, BENJAMIN

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/031,627	Applicant(s) KENDALL ET AL.	
	Examiner Benjamin Huh	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25, 27-41 and 55 is/are pending in the application.
4a) Of the above claim(s) 8, 35 and 38-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-12, 14-25, 27-32, 34, 36-37, 55 is/are rejected.
- 7) ☒ Claim(s) 13 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/22/07 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-12, 14-25, 27-32, 34, 36, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by BELLHOUSE et al. (US Patent No. 5,630,796). Bellhouse discloses a needless injection device and method of using the device including a rupturing membrane closure means (col. 8, ll. 1-5), substantially constant diameter driver chamber (upstream of rupturable membrane 34), substantially constant diameter duct section connected to driver chamber to receive gas therefrom, (constant diameter is within distal section of duct section, fig. 1, wherein the term substantially

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constant cross-sectional diameter is not fully defined by the specification and therefore since the cross-sectional diameter does not vary significantly the diameter of Bellhouse is seen to be substantially constant), dose of particles P upstream of closure means 34, fig. 8, divergently contoured nozzle 38 (downstream of duct) through which a quasi-steady flow travels, a quasi-steady gas flow that is substantially free of shockwaves, whereby the device generates shock waves and reflection waves upon rupturing the membrane. A bleed hole is disclosed to provide the pathway from pressurized gas to the driver chamber and a bleed valve is understood in the art to be of small size that it would substantially decouple the driver chamber with pressurized gas source (col. 4, line 62 - col. 5, line 2). Nozzle areas are chosen with respect to driver chamber pressure to be correctly expanded (col. 5, ll. 22-33; col. 5, ll. 60-65; col. 6, ll. 5-7). Different gases are selected to give different velocities (col. 6, ll. 5-7).

Some limitations recited in the claims are considered inherent. Establishing quasi-steady flow upstream of shock waves, claims 1, 5, 20, entraining and accelerating particles in quasi-steady flow, claims 1, 20, initiating a starting process when shock wave reaches duct section end, claim 2, 21, producing a secondary shock wave behind primary shock wave, claim 4, uniform velocity distribution over a cross-section, claims 7 & 28, movement of closure means col. 8 lines 1-31, claims 11, 32, no oblique shocks waves within the divergent nozzle, claims 12, 31, initiating (u-a) wave at duct end, claim 14, quasi-steady flow upstream of (u-a) wave, claim 15, expansion wave traveling upstream of membrane closure means, claim 16, and terminating quasi-steady flow when reflected expansion wave passes out of the device, claim 18 are considered

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inherent functions resulting from the generation of shock waves by rupturing a membrane at the downstream end of a driver chamber with a constant diameter duct section, and divergent nozzle.

The prior art discloses the same or similar structure recited in the claims and described in the specification with respect to fig. 5 and this similarity is the basis that the prior art device will inherently function as the claimed device and produce the associated waves and effects in use with shock waves. If Applicant argues that these claimed functions are not inherent Applicant should submit evidence that the prior art devices do not inherently possess these characteristics. See MPEP 2112, 2112.01, 2112.02.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over BELLHOUSE '880 as applied to claim 36 above, and further in view of BELLHOUSE '478. Bellhouse '880 teaches the claimed invention except for scoring the rupturable. Bellhouse '478 teaches scoring a rupturable membrane in order to limit shedding fragments (col. 8, ll. 52-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Bellhouse '478 in the

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device of Bellhouse '880 in order to facilitate rupturing the membrane preventing unwanted material from traveling to the target site.

Allowable Subject Matter

Claims 13 & 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 2/22/07 have been fully considered but they are not persuasive.

Applicant argues that Bellhouse does not disclose a substantially constant cross-sectional area, the examiner disagrees. Due to the lack of definition of the term "substantially" the examiner has utilized it in the broadest reasonable manner in which the cross-sectional area is seen not to vary significantly among the device wavering only slightly from an axis that could be placed in the middle of the device and therefore maintaining a "substantially constant cross-sectional area". Also, wherein it can be established as a portion of Bellhouse can be seen to be just the duct section since it does not clearly state the connection at which point the duct section is to the driver chamber, it can be seen to be connected via a portion. If the applicant desires the duct section to comprise a tube of constant cross-sectional area and NOT a "substantially cross-sectional area", the applicant is suggested to do so.

Applicant argues that the quasi-steady gas flow is substantially free of shockwaves, the examiner would like to note that the applicant's own specification clearly points out that the device of Bellhouse is capable of creating a quasi-steady flow that is substantially free of shock waves as is stated in applicant's own specification page 3 lines 16-19.

Applicant argues that the particles of Bellhouse are not substantially wholly entrained in the substantially shockwave-free quasi-steady flow to be accelerated thereby and expelled from the device, the examiner disagrees. Even though not all of the particles of Bellhouse may be in the quasi-steady gas flow from the gas delivered by the gas chamber, the specification discloses as well as the specification of the applicant's that the particles are accelerated and delivered by different mechanisms. Therefore, since the particles are in multiple different sections of the gas flow it is the examiner's position that there would be some particles located in the shockwave-free quasi-steady flow of the device and since not all the particles are needed to be deemed a dose, the amount of particles located in the section of the shockwave-free quasi-steady flow are seen to be a dose and delivered via the quasi-steady gas flow.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

